NOTE: Still open, last updated 7/12/01

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OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)

PROGRAM ANNOUNCEMENT: CHRONIC HEART FAILURE

VA QUERI
Quality Enhancement Research Initiative

Investigator-Initiated Research Priorities in Chronic Heart Failure

1. Purpose. The Veterans Health Administration (VHA) is focusing major resources and energy to improve the quality of the health care it provides and to create improvements that are measurable, rapid and sustainable. With the inauguration of the Quality Enhancement Research Initiative (QUERI) in early 1998, special emphasis has been placed on improving the quality of care in ten clinical areas that are prevalent in the VA: chronic heart failure, ischemic heart disease, diabetes, prostate disease, stroke, substance abuse, mental health (depression, schizophrenia), spinal cord injuries, HIV/AIDS, and cancer. For each of these areas, QUERI will identify gaps in science, practice, and information systems, and develop and evaluate methods for translating evidence of clinical effectiveness into practice. Additional information about QUERI is available on the VA web page at http://www.va.gov/resdev.

2. Synopsis. This announcement invites research proposals to enhance the quality of care for veterans with chronic heart failure (CHF) in three areas: assessing strategies to implement CHF clinical guidelines, identifying outcomes CHF patients think are important, and identifying end-of-life issues specific to patients with CHF. Projects may request up to four years and total costs of $750,000. However, HSR&D is especially interested in projects that can demonstrate results promptly and efficiently. For example, descriptive studies should not exceed two years. For the initial round of review, a brief planning letter (see Attachment A) must be received by December 10, 1998 and full proposals must be received by February 5, 1999. The first opportunity for proposal review will be March 1999, with the earliest possible funding date of April 1999. Thereafter, projects will require a Letter of Intent consistent with regular IIR policy, and proposal due dates are May 1 and November 1, until further notice. These investigator-initiated research projects are part of a comprehensive and merit-approved strategic plan that also includes a targeted research solicitation for service-directed research projects to improve health outcomes and cost effectiveness in CHF (see "Service Directed Research on Comprehensive, Integrated Programs for Optimizing Health Outcomes and Cost Effectiveness in Chronic Heart Failure," available this month on the VA web page at http://www.va.gov/resdev/hsr-sols.htm).

3. Background. Over four million American adults suffer from CHF and the annual incidence of new cases of heart failure in the U.S. ranges between 400,000 and 465,000. The incidence and prevalence of CHF increases with age, with two to three of every 100 people aged 65-74 having a diagnosis of CHF. The prevalence of CHF is expected to increase and the aging of the baby boom generation

ensures that CHF will be a major challenge to American society and the U.S. health care system over the next four decades. Among veterans, CHF is a prevalent, morbid, and costly condition. Heart failure also is a high-volume condition for the VA medical care system.

Heart failure is a lethal disease. In the Framingham study, approximately one-third of patients with CHF died within two years of their diagnosis. In the VA, about two-thirds of patients die within five years of their initial hospitalization for heart failure. Approximately 60 percent of patients with heart failure suffer an inexorable decline over the course of their disease, even if they are compliant with an optimal medical regimen. The other 40 percent of patients die suddenly.

Patients with heart failure are heavy users of health services because of the serious morbidity associated with their disease. From the patient's perspective, heavy use of services signifies frequent cyclical decompensation in their disease associated with physical, emotional, and spiritual suffering, poor functional status, an inability to pursue normal work and daily activities, and constant disruption of home and family life. Among patients with chronic conditions, CHF patients have some of the worst physical and social functioning.

In order to reduce this suffering, advance care planning between a patient and his or her physician is necessary to maximize the likelihood of a "good death," i.e., that the circumstances surrounding death are in line with the patient's values, beliefs, and preferences.

4. Research Priorities. Experts advising the VA have identified three high priority areas of research related to CHF. These are: implementation of clinical practice guidelines for CHF, CHF-specific patient outcomes, and end-of-life issues specific to CHF.

a. Effective Strategies for Implementing Guidelines for Heart Failure

Although five scientific bodies have issued guidelines for the technical care of patients with heart failure (Agency for Health Care Policy and Research, Canadian Cardiovascular Society, American College of Cardiology and American Heart Association, European Society of Cardiology, and the Advisory Council to Improve Outcomes Nationwide), the availability of sound clinical guidelines for heart failure does not ensure their implementation in routine clinical practice. The real challenge lies in getting clinicians to care for patients in accordance with current guidelines.

The VA specifies that evidence-based clinical guidelines will be implemented and attempts to document adherence by reviews of medical records. Directors of VA medical centers and VISNs are evaluated on the extent to which specified guidelines have been implemented within the VA facilities they supervise. However, the effectiveness of the VA's "inspection" approach to guideline implementation is not known.

One powerful way to change provider practice is by feedback of physician-specific and hospital-specific data. Patient-specific reminders attached to the medical chart at the time of the patient encounter have been shown to increase compliance with guidelines for preventive measures. However, we do not know the extent to which VA networks use these kinds of implementation strategies to change provider practices. Nor do we know which strategy might be the most cost-effective approach to implementing heart failure guidelines in the VA system. Should guideline implementation strategies vary with the characteristics of different medical centers?
Most importantly, if guidelines can change provider practice, do patient outcomes improve? Although this is unknown for CHF in particular, a systematic review by Grimshaw and Russel (1993) has shown that, in general, guidelines do affect the process and sometimes the outcomes of care. Of the 59

studies in the synthesis, 11 included outcome assessments. Nine of these 11 studies showed a small, but statistically significant improvement in patient outcomes.

This announcement invites research studies focused specifically on assessing the effectiveness of strategies to implement clinical guidelines for CHF into routine practice. The results of these studies can potentially improve clinicians' practice patterns and, consequently, improve the care and outcomes of patients with heart failure. Studies may focus on comparatively untested strategies including direct marketing to patients, academic detailing, and computer-based reminder systems. Proposals should include evaluations of how the process of care changes as well as how patients' outcomes are affected.

Examples of suitable research areas include, but are not limited to the following:

1. Are strategies that target patients as active participants in implementing guidelines for CHF effective and cost effective? How do they compare with strategies that target providers?

2. What should be the goals of guideline implementation in CHF? Improved compliance with process of care indicators (e.g., salt restriction, angiotensin-converting enzyme inhibitors)? Or improved risk-adjusted outcomes (e.g., improved outcomes, fewer hospitalizations, reduced mortality)?

3. What are the appropriate criteria to determine whether heart failure guidelines have been implemented at a given institution (e.g., VA medical center or VISN)?

For additional information on appropriate content areas and research methods, investigators should review HSR&D's 1998 solicitation entitled "QUERI: Common Issues in Implementation of Clinical Practice Guidelines," available on the VA web page at http://www.va.gov/resdev/hsr-sols.htm.

b. Health Outcomes Important to Patients with Chronic Heart Failure

Few, if any, published empirical studies have examined what CHF patients expect or hope from treatment for their disease. The medical system presumes what patients want is captured in such concepts as survival rates, complication rates, rates of heath services use, functional status, and health-related quality of life, but we do not know what outcomes are most important to patients with CHF. Nor do we know how patients assess trade-offs between, for example, length of survival and quality of life. As the VA and other health care systems strive to become more patient-centered, it is crucial to consider CHF patients as experts in defining important health-related outcomes.

Several generic and heart failure-specific scales have been developed and used in studies with patients with CHF (Wolinsky et al., 1998). However, it is not clear whether any of these scales is superior to the others (e.g., method of administration, sensitiveness to change over time, validity, reliability, respondent burden). In order to address these issues, this announcement focuses on studies identifying outcomes CHF patients think are important and determining how those outcomes can be best measured and tracked. HSR&D is very interested in outcomes important to patients and will issue a general solicitation in that area this month. This announcement solicits only research specific to CHF. Examples of suitable research areas include, but are not limited to the following:

1. Documenting the types of issues and concerns CHF patients identify as important.

2. Identifying CHF patients' expectations of their medical treatment.

3. Determining whether CHF patient concerns are adequately addressed in existing outcome measures.

4. Assessing the psychometric properties (e.g., validity and reliability) of these measures when applied to studies of CHF patients.

Proposals need to address the subjective and qualitative aspects of health services. Patient values, culture, preferences and individual needs are to be considered. Descriptive studies need to focus on identifying health-related outcomes from the patient's perspective. For additional information on appropriate content areas and research methods, investigators should review HSR&D's 1998 solicitation entitled "QUERI: Patient-Centered Outcomes," available this month on the VA web page at http://www.va.gov/resdev/hsr-sols.htm.

c. Care at the End-of-Life.

End-of-life research has mainly focused on patients with cancer, dementia or human-immunodeficiency-virus disease. Few studies have examined end-of-life issues in CHF patients. HSR&D is interested in studies to improve the quality of dying and expects to issue a general solicitation in that area in 1999. This announcement invites studies on end-of-life issues unique or especially important in CHF. Two types of studies may be proposed:

- Descriptive or analytic studies that seek to document end-of-life issues from the perspective of CHF patients. Cultural issues should be explicitly addressed.

- Single or multi-site demonstration projects that apply and evaluate an intervention designed to improve advance care planning and assist CHF patients in attaining a "good death."

Examples of specific research questions suitable for descriptive research include, but are not limited to the following:

1. How do patients with CHF define a "good death?" How do their caregivers define a "good death" for these patients? How do various definitions (e.g., patient, caregiver, clinician) of a "good death" impact end-of-life care?

2. What symptoms are most problematic for patients with CHF? How do these symptoms affect patients with CHF?

3. What issues do patients with CHF identify as important end-of-life issues (e.g., familial, emotional, spiritual, physical, economic concerns)? How can health care providers assist CHF patients find meaning at the end of life?

4. What kinds of understandings do CHF patients have about their prognosis? How do these understandings differ by race/ethnicity and gender?

5. What kinds of expectations do CHF patients have of palliative care? Hospice care (e.g., goals of hospice care, types of services)?

6. What kinds of care do CHF patients receive from the VA Palliative Care Program? Are caregivers satisfied with the end-of-life care that CHF patients receive in the VA Palliative Care Program?

7. What is the most accurate method for predicting prognoses of patients with CHF?

Examples of suitable areas for demonstration projects include, but are not limited to the following:

1. Evaluate the effectiveness and cost effectiveness of the VA Palliative Care Program (inpatient and home-based) for CHF patients. Effectiveness may be measured by symptom control, survival, quality of life, functional status, and patient and caregiver satisfaction.

2. Evaluate methods of training physicians to address end-of-life issues for CHF patients. What is the "best" method(s) for informing a CHF patient about their poor prognosis?

3. Evaluate methods for identifying and honoring CHF patient concerns and patient preferences for medical care at the end of life.

Investigators responding to this announcement should not duplicate the three-year program evaluation of the MediCaring National Demonstration Project. MediCaring, a joint project of the Center to Improve Care for the Dying and the VA, will assess the best practices in palliative and supportive care for patients with CHF or COPD. Investigators interested in having their institution considered as a VA demonstration site for the MediCaring Project may contact Bonnie Ryan, R.N. (202/273-6488).

5. Research Methods. Proposals developed in response to this announcement should use appropriately rigorous and efficient designs. Studies may use both quantitative and qualitative data and methods such as focus groups, face-to-face interviews, and surveys. The use of innovative research methods and culturally-sensitive instruments is encouraged.

In this solicitation, a "good death" is defined in a broad sense. Each proposal is expected to specify and justify the outcomes to be assessed in terms of their relevance to a "good death" and to explain how they will be defined, measured and evaluated.

Demonstration projects submitted for this announcement must:

- focus on well-designed interventions with clear applicability to multiple VA sites,
- test explicit hypothesis(es) about the relationship between the intervention and specified outcomes, and
- include a well-designed plan for obtaining and analyzing the intervention's effect on cost and quality of care

6. Application Process.

a. Eligibility. Investigators who hold a VA appointment of at least 5/8 time are eligible to apply for research support. Co-investigators, consultants, and support staff may be non-VA employees. Refer questions about eligibility to Robert Small at 202/273-8256 or robert.small@mail.va.gov.

b. Planning Letter. A planning letter is the first step in preparing a proposal. It will be used only for administrative purposes (for format, see Attachment A). The usual Letter of Intent (LOI) process required for HSR&D's Investigator-Initiated Research projects, whereby a detailed description of the project must be approved prior to submitting a full proposal, **does not apply** to this solicitation. Planning letters are due at the address listed in paragraph 9 ("Inquiries"), by the close of business on December 10, 1998. Facsimile and electronic mail copies will be accepted; address these to John

Francis, HSR&D Service, at FAX number 202/273-9007 or john.francis@mail.va.gov.

c. Proposal Preparation and Submission. For detailed instructions regarding preparation and submission of a full proposal, and general review criteria, applicants should refer to HSR&D's "Instructions for Submitting Investigator-Initiated Research Proposals" (available at all VA research offices and on the VA research home page at http://www.va.gov/resdev). Full proposals must be received by February 5, 1999.

d. Review. The first set of proposals based on this announcement will be reviewed at the Scientific Review and Evaluation Board subcommittee meeting in March 1999. Starting in June 1999, and until further notice, such proposals will be reviewed at regularly scheduled meetings of the Board, along with other IIR projects. The review is rigorous and standards very high; both scientific merit and expected contribution to improving VA health services are considered. Investigators are expected to develop and describe their research plan completely and in detail. Proposals recommended for approval will be considered for funding.

7. Funding. Studies submitted in response to this solicitation may not exceed four years or total costs of $750,000. Both short-term and long-term projects may be proposed, but HSR&D is particularly interested in projects that can demonstrate results in the shortest possible time. For projects that require more than two years, investigators are *strongly encouraged* to identify major milestones or project components for which interim results can be reported and published. In planning project budgets, applicants are reminded to adhere to R&D guidelines regarding allowable use of research funds for specific items. HSR&D expects to fund the first projects under this program in April 1999.

8. Coordination with QUERI. Principal Investigators will submit regular annual progress reports and requested updates to the Director, HSR&D, who will provide these to the appropriate QUERI Coordinating Center, through the Associate Director for QUERI.

9. Inquiries. For further information about this solicitation, contact:

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Attachment

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ATTACHMENT A

SAMPLE FORMAT FOR HSR&D PLANNING LETTERS

Provide a one-page letter addressed to the Review Program Manager (124F) that includes the following information:

1. Principal Investigator's name, affiliation, address, phone number, e-mail, and FAX number.

2. Name and affiliation of co-principal investigator, if applicable, and other key project participants.

3. Title and date of this solicitation.

4. Proposal title.

5. Specific focus of the proposed study.

6. Major methods to be used and type(s) of analyses to be performed.

7. (Optional) Name two or more scientists who are qualified to review the proposal; include name, degree, title, academic affiliation, complete address, telephone number, and e-mail address, if available.

8. Signature of the ACOS for R&D.